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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/046,504

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Steven J. Siegel

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3358

7590

05/04/2006

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/046,504	Applicant(s) SIEGEL ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt amendment and remarks filed 2/16/06. Claims 1 and 4 are amended. Claims 1-10 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Kino et al. (WO 94/10982, English abstract) is withdrawn in view of applicants' persuasive argument that Kino's microspheres are not designed for surgical implantation and Kino specifically states that surgical implantation is avoided.
2. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (J. Controlled Release, 1988, 203-212) is withdrawn because the content of haloperidol in the PLG microspheres is about 0.74 to 3.07 (Table 2; page 208, first full paragraph at the right column) and this content is much lower than the content of haloperidol of 20-40% now recited in claim 1. The withdrawal of the rejection renders applicants' argument over Cheng moot.
3. The rejection of claims 1-6 under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al. (US 6,130,200) in view of applicants' persuasive argument that in Brodbeck, the device is a viscous gel having biocompatible solvent present therein (abstract; column 8, lines 37-42; column 17, line 51 to column 18 line 9).

#### ***Claim Rejections - 35 USC § 103***

4. The rejection of claims 4-10 under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (J. Controlled Release, 1988, 203-212) is withdrawn in view of the reasons above that the

Art Unit: 1618

content of haloperidol in the PLG microspheres is about 0.74 to 3.07 (Table 2; page 208, first full paragraph at the right column) and this content is much lower than the content of haloperidol of 20-40% now recited in claim 1. The withdrawal of the rejection renders applicants' argument over Cheng moot.

5. The rejection of claims 7-10 under 35 U.S.C. 103(a) as being unpatentable over Brodbeck et al. (US 6,130,200) is withdrawn in view of applicants' persuasive argument that in Brodbeck, the device is a viscous gel having biocompatible solvent present therein (abstract; column 8, lines 37-42; column 17, line 51 to column 18 line 9).

*Claim Rejections - 35 USC § 112*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 2 recites the limitation "biodegradable polymer comprises" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not provide antecedence polymer that comprises, which opens up the claims.

9. Claim 3 recites the limitation "delivery system comprising ..." in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. The language of claim 1 is consisting essentially of and the comprises opens up the claim language.

Art Unit: 1618

For claim 2, the rejection may be overcome by stating that biodegradable polymer is polylactide or lactide-co-glycolide copolymer.

For claim 3, the rejection may be overcome by stating that the polymer in the delivery system of claim 1 is in amounts 50-100% polylactide and 0-50% polyglycolide.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al. (US 6,166,173).

Mao discloses biodegradable medical implant devices that incorporates from about 1% to about 65% active agent (abstract, column 21, lines 8-11; column 22, lines 34-44), the active agent includes antipsychotic drugs (column 20, lines 1 and 2); the biodegradable polymers are polyesters (column 2, lines 27-33; column 12, lines 52, 53, 61, 62; column 13, lines 3, 4, 15).

While there is long list of drugs, if the desire is to incorporate antipsychotic drugs, then any of the antipsychotic drugs such as clozapine, haloperidol and risperidone (column 20, lines 1 and 2) can be used. The biodegradable implant is prepared by melt process (column 22, lines 34-40) or by compression molding at 50 °C (column 24, lines 47-58). Regarding claim 9, the antipsychotic drug may have effect over schizophrenia. Mao discloses that a single entity or combination of entities may be used and thus, regarding claim 10, the antipsychotic drugs may be used in combination with the expectation of producing synergistic effect. Therefore, it would

Art Unit: 1618

have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the biodegradable implant of Mao by compression molding of discs or melt process and incorporate the amount of active agent such as haloperidol or clozapine or risperidone antipsychotic drugs in amounts of from 1-65% that would be effective to produce the desired antipsychotic effect.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
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